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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,061	01/28/2004	James F. McGuckin JR.	1211 DIV	2289

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EXAMINER

THANH, QUANG D

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,061	MCGUCKIN ET AL.	
	Examiner	Art Unit	
	Quang D. Thanh	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is responsive to the preliminary amendment filed on 1/28/04. As directed by the amendment, claims 1-22 have been cancelled, and new claims 27-34 have been added. Thus, claims 23-34 are presently pending in this application.

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/877,639, filed 06/08/01. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application, if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 23-26, 28 and 30-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,676,698. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of U.S. Patent No. 6,676,698 disclose a method of using a delivery device (balloon catheter) and a vascular device, which substantially comprising all the claimed elements including a delivery device with a balloon (claim 7); a vascular device having a collapsed position (pre-deploying state) and a memorized position (first expanded diameter in claim 4), and expandable to the memorized position in response to body temperature (claim 4) and to an expanded position (enlarged diameter) by the inflation of the balloon (claim 7) and returnable to the memorized position (claim 4); and a sheath (claim 4).

4. Claims 23-26, 28, 30-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,527,800. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-23 of U.S. Patent No. 6,527,800 disclose a method of using a delivery device (balloon catheter) and a vascular device,

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which substantially comprising all the claimed elements including a delivery device with a balloon (claim 5); a vascular device having a collapsed position and a memorized position (first expanded diameter in claim 2), and expandable to the memorized position in response to body temperature (claim 4) and to an expanded position (enlarged diameter) by the inflation of the balloon (claim 5) and returnable to the memorized position (claim 13); a sheath (claim 21).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 23-26 and 28-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Frantzen (6,042,606).

7. Re claim 23, Frantzen discloses a vascular system comprising: a balloon catheter having an elongated shaft P and an expandable balloon B (fig. 15); a vascular device 10 mounted over the expandable balloon (fig. 15) and composed of shape memory material (Nickel-Titanium, col. 6, lines 40-42) and having a collapsed position 10 (fig. 7) and a memorized position 10' (fig. 8), the vascular device expandable to an expanded position to engage the vessel walls and returnable substantially to the

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memorized position to bring the walls radially inwardly (in this case, the stent 10' inherently is capable of being expanded into a larger expanded position 10'' (fig. 9) if and when the balloon is overinflated, and since the stent has a superelasticity and shape memory effects, thus it would return to its memorized position 10' after the deflation of the balloon .

8. Re claims 24-26, wherein the vascular device is expandable first to the memorized condition in response to exposure to body temperature (col. 11, lines 8-16) and subsequently expanded to the expanded position by inflation of the balloon (col. 11, lines 1-7); wherein the vascular device is expandable to the expanded position as the device is substantially simultaneously exposed to body temperature and the balloon is inflated (col. 11, lines 1-16); the vascular device is connected to the balloon (fig. 15)

9. Re claims 28-34, further comprising a sheath S (fig. 15), the balloon catheter positioned within the sheath (fig. 15), and wherein release of the vascular device from the sheath enables it to expand to the memorized condition (col. 10, line 60 to col. 11, line 2); wherein the vascular device is formed from a laser cut tubular member (col. 9, lines 51-64); wherein the balloon catheter includes an outer sheath S slidable with respect to the catheter shaft to expose the vascular device (fig. 15); wherein the vascular device is maintained in a collapsed configuration inside the sheath at a temperature below its transition temperature (col. 11, lines 8-10); wherein the catheter includes an inflation lumen communicating with the balloon (inherently it must have an inflation lumen in order to supply gas from gas source G to the balloon catheter B, col. 10, lines 60-66), wherein inflation of the balloon expands the device to a diameter larger

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10' than the diameter of the vascular device 10 and subsequent deflation of the balloon results in the device contracting towards the memorized position 10' (figs. 15-17).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen in view of Wijay (5,643,278). Frantzen discloses the claimed invention having all the features including the vascular device being mounted on the balloon (fig. 15), except that it is silent regarding a pair of looped sutures connecting the vascular device to the balloon. However, Wijay teaches a means of attaching the stent to the balloon in the form of spring coil or a thin layer of glue (col. 4, lines 35-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to include an attachment means, as suggested by Wijay, such as a thin layer of glue, spring coils or surgical threads, for the purpose of connecting the vascular device to the balloon securely thus ensuring the proper position of the vascular at the desired location of the blood vessel.

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Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boylan et al. '646 discloses a curved nitinol stent. Burmeister et al. '461 discloses a stent for supporting tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang D. Thanh whose telephone number is (571) 272-4982. The examiner can normally be reached on Monday-Thursday & alternate Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson can be reached on (571) 272-4887. The Central FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for all communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Quang D. Thanh
Patent Examiner
Art Unit 3764
(571) 272-4982

August 10, 2005

